

## REMARKS

The present amendment cancels claims 2, 30 and 31 and adds new claims 35 and 36. Thus, claims 1, 3-21, 23-29 and 32-36, are presented for consideration upon entry of the present amendment, which is respectfully requested.

Claims 1-21 and 23-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,626,950 to Brown et al. (hereinafter "Brown"). Applicant respectfully traverses this rejection. Claims 2, 30 and 31 have been canceled therefore these rejections are moot.

Independent claim 1 now provides, in part, a prosthetic device including at least one layer having at least partially oriented fibers, a base component and a stabilization area, wherein the fibers are aligned essentially in parallel to the insertion axis of the prosthetic device that is in a direction perpendicular to a top surface of the base component and the fibers form a brush-like structure, wherein more than 50% of the fibers are aligned essentially in parallel to the insertion axis of the prosthetic device.

Brown relates to the field of tissue repair and the use of composite scaffold implants and scaffold fixation devices. Brown provides for an implant consisting of a foamed polymer and a ceramic base component.

The Office Action acknowledges that Brown does not teach that more than 50% of the fibers are aligned essentially in parallel to the insertion axis which is a direction perpendicular to the top surface of the base component, which is now recited in independent claim 1.

The present application clearly discloses that a high percentage of fibers must be aligned in the same direction and are designed in this manner to result in a brush-like

structure. Thus, the arrangement of the fibers in the prosthetic device of the present application are not arbitrary.

The Office Action suggests that the polymeric phase (22) of Brown provides for the fiber layer of the present application because it is made up of natural biopolymers including collagen and elastin. Applicant respectfully disagrees.

To the contrary, Brown is silent about fibers being present in the polymeric phase (22), let alone disclosing the alignment of fibers, as recited in claim 1. For example, in column 6, beginning on line 54, Brown merely discloses that in an alternative embodiment the ceramic phase (24) may be in the form of a porous polymer matrix with inclusion of short ceramic fibers or particulates for reinforcing the ceramic phase (24). At most, Brown merely discloses arbitrarily arranged, short fibers in a ceramic phase, which cannot comprise a brush-like structure due to its shortness.

Furthermore, one skilled in the art would not arrive at the alignment or orientation of the fibers as recited in claim 1 from the disclosure of Brown.

First, since Brown does not show fibers in the polymeric phase (only the ceramic phase), it is not contemplated in Brown to arrange the fibers in any particular orientation, let alone as described in claim 1.

Second, it is not important for the purpose of the fibers or particulates in the ceramic phase of Brown to have a particular orientation. The "short" fibers of Brown are integrated in the porous ceramic foam layer for reinforcement, and do not extend beyond the foam layer. In contrast, the fibers of the present application are purposely arranged for attaining a brush-like structure, and thus reproducing cartilage or cartilage tissue. Therefore, the short fibers of Brown do not result in a brush-like structure as provided in claim 1 of the present application.

As a result, Brown fails to provide for a layer having at least partially oriented fibers, wherein the fibers are aligned essentially in parallel to the insertion axis of the prosthetic device that is in a direction perpendicular to a top surface of the base component and the fibers form a brush-like structure, wherein more than 50% of the fibers are aligned essentially in parallel to the insertion axis of the prosthetic device, as recited in claim 1. Thus, for at least the reasons provided above, independent claim 1 is not obvious over Brown.

Accordingly, Applicant submits that independent claim 1, as well as claims 3-21, 23-29 and 32-34 that depend therefrom, are not obvious over Brown.

Furthermore, the Office Action has objected to the use of the ending "-like" of the feature "cartilage-like" tissue, thus Applicant has amended claim 1 by deleting the phrase "-like". In addition, in claim 1, the language "comprising" has been removed and the phrase "axis of insertion" has been clarified to indicate a direction perpendicular to the top surface of the base component. Applicant respectfully requests reconsideration and withdrawal of these objections.

The Office Action has also objected the use of the ending "-like" of the feature "brush-like" structure. This feature is clearly illustrated in Fig. 1 showing the fibers of the present application are designed and arranged such that their structure is comparable with the structure of a brush. This feature is further described in paragraph [0021] of the present application which provides that the brush-like structure is formed by fibers in a direction perpendicular to the base component (4). Stabilization area (3) acts as an adhesive component to hold together the base component and the fibers in the specific brush-like arrangement, as clearly shown in Fig. 1.

The brush-like structure of the fibers provide the device with properties of cartilage or cartilage tissue, i.e., stability and at the same time resilience, while further providing the characteristic of friction, lubrication, and wear in a joint. As described in paragraph [0017] of the present application, the specific alignment of the fibers, usually

in a direction perpendicular to a top surface of the base component facing the fibers, perfectly mimics the cartilage or cartilage tissue providing an excellent mechanical stability. In addition, the fibers provide a basis for the ingrowth of articular chondrocytes, resulting in a rapid cartilage or cartilage tissue growth, and thus assuring long-term cartilage or cartilage tissue replacement. For at least the reasons described above, the use of the phrase "brush-like" structure and its benefits are clearly disclosed, thus rendering the scope of the claim ascertainable. Applicant respectfully requests reconsideration and withdrawal of this objection.

Applicant respectfully disagrees with the objection to the language "essentially" in claim 1. In particular, the term "essentially" has to be understood in respect of the whole context of the claim and description. In particular, the claim reads that the fibers are aligned essentially in parallel to the insertion axis of the prosthetic device, i.e. in a direction perpendicular to a top surface of said base component and thus form a brush-like structure. Figure 1 clearly shows that not each and every fiber is exactly in parallel with the other fibers, thus the fibers are "essentially" aligned in parallel. Even if the features do not give a restriction to particular angles, it is clear how the fibers are aligned "essentially" in parallel from the figures and specification.

Finally, the Office Action alleges that there is no difference between the term "porosity" of Brown and "liquid capacity" as claimed in the present application. Furthermore, the Office Action alleges that "porosity" is defined as being able to absorb fluids/liquids. Applicant respectfully disagrees.

To the contrary, the ASTM International (American Society for Testing and Materials) (particularly Committee: F04 Medical Devices; Standard: F2150; porosity n), defines the term "porosity" as "the property of a solid which contains an inherent or induced network of channels and open spaces. Porosity can be measured by the ratio of pore (void) volume to the apparent (total) volume of the porous material and is commonly expressed as a percentage". This demonstrates that porosity is completely distinguished from the absorbing ability of the fibers of the present application, which,

according to their absorbing ability, can transform to a gel-like state (see paragraph [0032]).

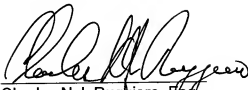
New dependent claims 35 and 36 have been added to point out various aspects of the present application. Support for new claim 35 can be found in the originally filed specification on page 13, beginning on line 14. Claim 35 provides that the stabilization area is an absolute or selective cell barrier layer for preventing cells and blood from diffusing from the base component into the brush-like fiber structure. Applicant submits that Brown does not disclose or suggest any cell barrier layer; instead Brown merely discloses a general cell structure obtained by implantation or in vitro seeding of the cells. Thus, new claim 35, which is dependent from now allowable claim 1, is not obvious over Brown.

Support for new claim 36 can be found in the originally filed specification on page 9, lines 20-22. Claim 36 provides for fibers that are designed to form a gel or transform to a gel-like state when absorbing a liquid. Claim 36 depends from dependent claim 6, which depends from now allowable independent claim 1. Applicant submits that new claim 36 is not obvious over Brown.

In view of the foregoing, Applicant respectfully submits that all claims present in this application patentably distinguish over the cited prior art reference. Accordingly, Applicant respectfully requests favorable reconsideration and withdrawal of the rejection of the claims. Also, Applicant respectfully requests that this application be passed to allowance.

If for any reason the Examiner feels that consultation with Applicant's attorney would be helpful in the advancement of the prosecution, the Examiner is invited to call the telephone number below.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Charles N.J. Ruggiero", written over a horizontal line.

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